

NDA 20,902

Jo Hendt

Review # 1

Sponsor & Address: Merck Research Laboratories
Agent: Johnson & Johnson o Merck Consumer
Pharmaceuticals Co.
Ft. Washington, PA

Date of Submission: September 30, 1997 FEB 27 1998

Date of Review: February 27, 1998

Product Name: Pepcid AC Gelcaps

Generic Name: Famotidine

Dosage Form: Oral Caplet 10 mg

Pharmacologic Category: Histamine H₂-receptor antagonist/
antiulcer agent.

Composition:

INGREDIENTS

mg/Tab

Famotidine
Pregelatinized Starch
Microcrystalline Cellulose
Magnesium Stearate
Talc

Hydroxypropyl Methylcellulose
Castor Oil

Subtotal

Sodium Lauryl Sulfate

Subtotal

Total Weight

2. The correspondence of November 6, 1997 provides for supplemental patent information for Pepcid AC[®] Acid Controller[™] Gelcaps.
3. BC Amendment of June 24, 1998 was in response to additional questions on Biopharmaceutics, Chemistry and Labeling (November 24, 1997).

CONCLUSIONS & RECOMMENDATIONS:

On the basis of the deficiencies noted in this review, the OTC Labeling Review deficiencies and the compliance recommendation to "Withhold" approval because of facility deficiencies, it is recommended that the NDA be not approved on the basis of chemistry and that the deficiencies be provided to the applicant by letter. The CSO will draft the deficiency letter with the appropriate FDA signature block.

/S/

Joseph Sieczkowski, Ph.D.
Review Chemist, HFD-180

Sept. 28, 1998

/S/

Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180

9/29/98

cc:

NDA 20-902

HFD-180/L.Talarico

HFD-180/Div File/NDA 20-902

HFD-180/E.Duffy

HFD-180/J.Sieczkowski

HFD-181/M.Folkendt

R/D Init by: E.Duffy/

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NDA 20,902
Page 2

Indications: For relief of heartburn, acid indigestion and sour stomach and for prevention of these symptoms brought on by provocative foods and beverages.

Related NDAs: NDA 19,462 (PEPCID Tablets, Merck)
NDA 20,325 (PEPCID AC Film-Coated Tablets, Merck)
NDA 20,801 (PEPCID AC Chewable Tablets, Merck)

REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA
Original Summary

SUMMARY AND EVALUATION:

This NDA provides for 10 mg PEPCID (famotidine) oral caplets (Gelcaps) as an alternate dosage form to an already approved film coated tablet as an OTC therapy for the prevention and treatment of upper gastrointestinal symptoms of heartburn, acid indigestion and sour stomach. Pepcid is a well established approved therapeutic entity. Tablet, suspension and injectable forms of PEPCID have been approved for use in the treatment of active duodenal ulcer, active benign gastric ulcer and pathological hypersecretory conditions and in the maintenance therapy for duodenal ulcer patients after healing the ulcer. Since the drug has already been found to be safe and is the subject of 5 approved NDAs with extensive clinical exposure, there is no need for additional preclinical studies. Approval of this NDA is recommended by Pharmacology.

/s/

2/27/98

Jasti B. Choudary, B.V.Sc., Ph.D.

CC:
NDA
HFD-180
HFD-181/CSO
HFD-180/Dr. Choudary

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APPEARS THIS WAY ON ORIGINAL